

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

DEC 12 2012

Aesculap® Implant Systems S4 Spinal System
October 23, 2012

COMPANY: Aesculap® Implant Systems, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 3005673311

CONTACT: Lisa M. Boyle
610-984-9274 (phone)
610-791-6882 (fax)

TRADE NAME: S4

COMMON NAME: Pedicle Screw System

REGULATION NUMBER: 888.3070 – Orthosis, Spinal Pedicle Fixation For Degenerative Disc Disease
888.3070 – Orthosis, Spinal Pedicle Fixation
888.3070 - Orthosis, Spondylolisthesis Spinal Fixation
888.3050 – Appliance, Fixation, Spinal Fixation

PRODUCT CODE: NKB, MNI, MNH, and KWP

REVIEW PANEL: Orthopedics

PURPOSE FOR PREMARKET NOTIFICATION

The S4 Spinal System described in this submission represents a line extension to the system. The purpose of the line extension is to include additional rod connectors to the system.

SUBSTANTIAL EQUIVALENCE

Aesculap® Implant Systems, Inc. believes that the S4 Spinal System is substantially equivalent to the S4 Spinal System (K112551/K062085), the Aesculap Spine System Evolution (K001080), and the Depuy Spine Expedium Systems (K033901, K063156, K073126, K073364, K081898).

DEVICE DESCRIPTION

The S4 Spinal System consists of polyaxial screws and monoaxial screws of varying diameters and lengths, various hook styles, rods of varying lengths, fixed and adjustable cross-connectors, and various styles of rod connectors. All implant components are top loading and top tightening. The S4 Spinal System is manufactured from Titanium and Titanium alloy in accordance with ISO 5832/3 and ISO 5832/2.

INDICATIONS FOR USE

The S4 Spinal System is intended for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation. Fixation is limited to skeletally mature patients and is

intended to be used as an adjunct to fusion using autograft or allograft. The device is indicated for treatment of the following acute and chronic instabilities or deformities:

- 1) degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- 2) spondylolisthesis,
- 3) trauma (i.e., fracture or dislocation),
- 4) spinal stenosis,
- 5) deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
- 6) tumor,
- 7) pseudoarthrosis, and
- 8) failed previous fusion.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The components of the Aesculap® Implant Systems S4 Spinal System are offered in similar shapes and sizes as the predicate devices. All the components are manufactured from Titanium and Titanium Alloy, which is the same material as the predicate devices.

PERFORMANCE DATA

As recommended by the FDA Guidance for Spinal System 510(k)'s, non-clinical testing was performed to demonstrate that the S4 Rod Connectors are substantially equivalent to other predicate devices. The following testing was performed:

- Static Axial Compression Bending per ASTM 1717-11a
- Dynamic Axial Compression Bending per ASTM F1717-11a
- Static Torsion per ASTM 1717-11a

The results of these studies showed that the subject Aesculap S4 Rod Connectors meet or exceed the performance of the predicate devices, and the device is therefore found to be substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 12, 2012

Aesculap Implant Systems, Incorporated
% Ms. Lisa Boyle
Senior Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K123352

Trade/Device Name: S4 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP
Dated: October 26, 2012
Received: November 7, 2012

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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A. INDICATIONS FOR USE STATEMENT**510(k) Number:** K123352**Device Name:** **S4 Spinal System****Indications for Use:**

The S4 Spinal System is intended for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation. Fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion using autograft or allograft. The device is indicated for treatment of the following acute and chronic instabilities or deformities:

- 1) degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
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- 6) tumor,
- 7) pseudoarthrosis, and
- 8) failed previous fusion.

Prescription Use X and/or Over-the-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)

Division of Orthopedic Devices

510(k) Number: K123352